DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

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December 3, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-14

Anne-Lise Berger, President
Scan Select, Inc.
6719 15th NW
Seattle, Washington 98117

WARNING LETTER

Dear Ms. Berger:

On October 26, 2001, Investigator Mark E. Moen conducted an inspection of your firm. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations [21 Code of Federal Regulations (CFR) 123]. The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

The product covered during this inspection was refrigerated, canned anchovy fillets from [redacted]. At the conclusion of that inspection a list of violations (Form FDA 483) was presented to you. This HACCP violation causes your imported products to be adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Specifically,

> **You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health in order to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for refrigerated, canned anchovy fillets from Norway.**

The above HACCP violation is not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the HACCP violations. Failure to promptly correct these violations may result in regulatory action without further notice such as seizure and/or injunction. Furthermore, your firm and the foreign processor may be placed on import alert and future shipments of the product may be subject to detention without physical exam.

During the inspection, Investigator Moen notified you that your firm had no written verification procedures for canned fish balls imported from [redacted]. All seafood products imported by you must have written verification procedures which include both product specifications and one of the six affirmative steps. These requirements were provided in previous correspondence with you.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply to these concerns should be addressed to Thomas S. Piekarski, Compliance Officer, at the address given above.

Sincerely,

Charles M. Breen
District Director